NF-I-35 5/14/98

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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

98-PHI-20

WARNING LETTER

April 23, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 5/12/98
Reviewed by: Ann D. Kuna

Stewart Heydt, M.D.
CEO/President
Geisinger Medical Center
100 N. Academy Ave.
Danville, PA 17822

Facility ID: 113704

Dear Dr. Heydt:

On April 7, 1998, an investigator from the Food and Drug Administration (FDA) visited your satellite facility, Penn State Geisinger Medical Group, 300 Highland Ave., Lewistown, PA 17044, and collected information that revealed a serious regulatory problem involving the mammography operations at this facility. Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either 1) are being evaluated for accreditation by that body, or 2) have been accredited by that body are entitled to a certificate.

The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility is qualified to perform quality mammography. The evidence collected by the FDA shows that you have performed mammography without a valid FDA MQSA Certificate.

The original FDA MQSA Certificate for your Lewistown facility expired on September 11, 1997. This facility had applied to the American College of Radiology for reaccreditation on August 22, 1998. To allow adequate time to review your accreditation application, this facility received a "6 Month Provisional Certificate" and was listed as a "Reinstated facility undergoing accreditation". This provisional certificate expired on March 10, 1998. Our investigator found that the Lewistown facility performed mammography examinations after this date and without a valid certificate or Interim Notice on the following days: 3/11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27/98. Approximately [redacted] patients were given mammography exams during this time period.

Performing mammography without a valid certificate is a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, assessing civil money penalties up to $10,000 or obtaining a court injunction against further mammography.

FDA became aware of this situation from a MQSA inspector from the Commonwealth of Pennsylvania who inspected the Lewistown facility on March 27, 1998 and observed that their FDA MQSA Certificate had expired. She advised the Senior Technologist to discontinue performing mammography and they subsequently stopped performing mammography.

Our investigator on April 7, 1998 had determined that there was confusion as to statements made by a MQSA inspector from the Commonwealth of Pennsylvania when the inspection appointment was confirmed. However, FDA's letter dated March 2, 1998 to the Lewistown facility does clearly state: "Under the Mammography Quality Standards Act (MQSA) of 1992, **once your certificate expires, you are no longer certified and cannot continue to offer mammography services".**

This facility then applied to the FDA for an Interim Notice which would allow them to lawfully provide mammography services while the ACR completes review of your reaccreditation application. The Lewistown facility received this Interim Notice on March 31, 1998 and it had an expiration date of May 15, 1998. Mammography exams were resumed on April 1, 1998.

Please inform this office in writing within fifteen (15) working days from the date you receive this letter. **of the specific steps you will take to assure that in the future your facility will only perform mammography examinations when you are in possession of a valid FDA MQSA Certificate.** Please submit your response to

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

Finally, you should understand that there are other FDA requirements pertaining to mammography. This letter only pertains to the issue of the performance of mammography under a valid FDA MQSA Certificate and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food & Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,

Charles Thorne
Acting District Director
Philadelphia District

cc: Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

Thomas Charles, Vice President Operations - Western Region
2520 Green Tech Drive, Suite AA
State College, PA 16803

Robert E. Kramer, M.D., Medical Director
Penn State Geisinger Medical Group
300 Highland Avenue
Lewistown, PA 17044

Brenda Moore, Clinic Operations Manager
Penn State Geisinger Medical Group
300 Highland Avenue
Lewistown, PA 17044

Rebecca Hunter
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Suite 6010 Lee Park
555 North Lane
Conshohocken, PA 19428